REMARKS

Applicants have cancelled all previously pending claims and added claims 35-59. Literal support for these claims can be found in previous claims 1-34, with the exception of the addition of the limitations regarding: (1) the amount of active compound and gelling agent being about 30-90% w/w of the total composition; and (2) the core matrix being a single layer. Support for the first limitation can be found at page 14, lines 4-15, of the specification, while the latter limitation makes explicit an inherent feature of the invention described in the application and examples. For instance, example 2 (pages 33-41) discloses numerous sustained-release compositions with both of these characteristics.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

I. The Rejection over Balandrin *et al.* in view of Rork *et al.* and *Vice Versa*

Claims 1-5, 7-11, 14-20, 22-27, and 29-34 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Rork *et al.*, U.S. Patent No. 5,582,838, in view of Balandrin *et al.*, U.S. Patent No. 5,506,268, and *vice versa*. Applicants respectfully traverse this ground for rejection.

A. The Examiner's Basis for the Rejection

Rork *et al.* is alleged to teach sustained-release formulations comprising an active agent core and a film coating. The core is made of: (a) diethylisovaleramide or bromo-isovaleryl-urea, and (b) a polymer that forms gel beads upon hydration and dissolves slowly (specifically sodium acrylate or carboxymethylene). The film coating is made of, *inter alia*, ethyl cellulose or cellulose acetate.

Balandrin *et al.* is alleged to teach the use of an isovaleramide tablet, capsule, or drop, for treating CNS disorders.

The examiner alleges that one of skill in the art would be motivated to use the isovaleramide tablets of Balandrin *et al.* or the diethylisovaleramide of Rork *et al.* in the sustained-release composition of Rork *et al.* with an expectation to prolong the compounds' therapeutic effects taught by Balandrin *et al.*. The examiner alternatively alleges that it would have been obvious to use the sustained-release formulation of Rork *et al.* with the isovaleramide of Balandrin *et al.* in order to provide a sustained-release of isovaleramide for a prolonged treatment of CNS disorders such as anxiety or restlessness.

B. Applicants Response

Newly added claims 35-59 require that the amount of active compound and gelling agent be about 30-90% w/w of the composition. As discussed on page 33, lines 25-27 of the application, this is a very high drug load for such a water-soluble drug. Neither Balandarin *et al.* nor Rork *et al.* teach or suggest such a formulation, nor do these references provide a reasonable expectation that such a composition could be made successfully.

In addition, neither of these references teach or suggest a composition having a single-layer core matrix. Rork *et al.* teaches a two-layer core matrix, and Balandarin *et al.* does not describe any specific formulation at all.

Accordingly, the cited references do not make out a *prima facie* case of obviousness. Withdrawal of this ground for rejection is respectfully requested.

II. The Rejection over Balandrin *et al.* in view of Rork *et al.* and Pankhania *et al.*

Claims 6, 12, 13, 21, and 28 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Rork *et al.*, U.S. Patent No. 5,582,838, in view of Balandrin *et al.*, U.S. Patent No. 5,506,268, and further in view Pankhania *et al.*, U.S. Patent No. 5,415,871. Applicants respectfully traverse this ground for rejection.

A. The Examiner's Basis for the Rejection

Pankhania *et al.* is alleged to teach xantham gum as a gelling agent in sustained-release formulations for pharmaceutically active agents such as sedatives, and is admittedly not described in Balandrin *et al.* or Rork *et al.* The examiner alleges that it would have been obvious to use xantham gum as the gel forming polymer taught by Rork *et al.*, containing diethylisovaleramide or isovaleramide taught by Rork *et al.* and Balandrin *et al.*

B. Applicants Response

Newly added claims 35-59 require that the amount of active compound and gelling agent be about 30-90% w/w of the composition. As discussed on page 33, lines 25-27 of the application, this is a very high drug load for such a water-soluble drug. Pankhania also does not teach or suggest such a formulation or provide a reasonable expectation that such a composition could be made successfully. Accordingly, the cited references do not make out a *prima facie* case of obviousness.

It is respectfully submitted that Applicant's claimed invention is not obvious over any combination of Rork *et al.*, Balandrin *et al.*, and Pankhania *et al.*, and therefore, withdrawal of this ground for rejection is courteously requested.

III. Claims regarding duration of effect

In the Office communication dated 5/2/03, the examiner stated that the "instant claims do not state as to the duration over which the released active agent takes place." Applicants direct the examiner's attention to claims 37 and 38 (analogous to cancelled claims 3 and 4), which state that the composition releases the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of active ingredient for at least 8 or 12 hours, respectively. Applicants submit that this provides and additional reason why claims 37 and 38 are patentable over the prior art.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to our Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date Sept 9, 2003

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge deposit account No. 19-0741 for any such fees; and applicant hereby petitions for any needed extension of time.